

## Professional Information

**SCHEDULING STATUS:** S0

### PROPRIETARY NAME AND DOSAGE FORM

TIGER BALM® RED, ointment

### COMPOSITION

TIGER BALM RED contains natural camphor 11,0 % w/w, levomenthol (menthol) 10,0 % w/w, cajuput oil 7,0 % w/w, dementholised mint oil 6,0 % w/w, clove oil 5,0 % w/w as well as cassia oil, hard paraffin and yellow soft paraffin.

### CATEGORY AND CLASS

Complementary medicine: Health supplement

D 34.12 Multiple substance formulation

### PHARMACOLOGICAL ACTION

#### Pharmacokinetic properties

Camphor and menthol are well absorbed when applied topically, and produce a local effect.

Camphor is readily absorbed from all administration sites. It is hydroxylated in the liver to yield hydroxycamphor metabolites which are then conjugated with glucuronic acid and excreted in the urine.

After absorption, menthol is excreted in the urine and bile as a glucuronide.

#### Pharmacodynamic properties

Menthol and camphor have mild analgesic and rubefacient properties. Camphor is a mild counter irritant.

## **INDICATIONS**

For the temporary relief of muscular aches and pains, as well as rheumatic pain, strains, sprains, bruises, dislocations and lumbago (lower back pain).

## **CONTRAINDICATIONS**

Hypersensitivity to any of the ingredients of TIGER BALM RED (refer to COMPOSITION).

Skin disease, open wounds, inflamed or irritated skin.

Use in infants and children under 2 years of age, due to the risk of respiratory collapse.

Asthma or other diseases of the respiratory tract that involve hypersensitivity of the airways.

## **WARNINGS AND SPECIAL PRECAUTIONS**

Avoid contact with mucous membranes such as the delicate and moist linings in or around the eyes, mouth and nose.

Do not bandage areas where TIGER BALM RED was applied.

Do not apply to the nose or inhale.

Do not use TIGER BALM RED near the nose of infants or young children, as other similar products have been reported to cause apnoea, instant collapse or laryngospasm, throat spasms or breathing difficulties in infants and young children following nasal use; see CONTRAINDICATIONS.

Health supplements cannot substitute a healthy lifestyle, they are intended only to complement health.

## **INTERACTIONS**

When combining TIGER BALM RED with other topical pain-relieving products containing similar ingredients, the dosage effect may be multiplied. When using any health supplement alongside other medications, vitamins and dietary supplements, it is always advisable to consult your doctor or pharmacist.

**HUMAN REPRODUCTION**

Safety in pregnancy and breastfeeding has not been established (refer to CONTRAINDICATIONS).

Camphor crosses the placenta.

Avoid excessive use during pregnancy and breastfeeding.

**DOSAGE AND DIRECTIONS FOR USE**

TIGER BALM RED is for external use only.

Adults and children over 2 years of age: Rub gently on the affected parts of the skin as necessary, usually 2 or 3 times a day. Wash your hands after use.

Contact a healthcare practitioner if your condition worsens or do not improve after 2 weeks.

**SIDE EFFECTS****Immune system disorders**

*Frequency unknown:* Hypersensitivity reactions such as rashes, contact dermatitis, redness or irritation of skin.

**Respiratory, thoracic and mediastinal disorders**

*Frequency unknown:* Can cause apnoea, instant collapse or laryngospasm, throat spasms or breathing difficulties in infants and young children following nasal use.

**General Disorders and Administration site conditions**

*Frequency unknown:* Burning pain, burns or blistering at application site.

If these side effects occur, discontinue use and seek medical advice immediately.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT**

Side effects, such as skin irritation, may be experienced after an overdose of TIGER BALM RED (see SIDE-EFFECTS).

**Misuse**

Swallowing of the ointment might cause gastrointestinal symptoms like vomiting and diarrhea. Treatment is symptomatic. Acute poisoning was observed after significant accidental consumption, with nausea, vomiting, abdominal pain, headache, vertigo, feeling hot/flushing, convulsions, respiratory depression and coma. Patients with severe gastrointestinal or neurological symptoms of poisoning should be observed and treated symptomatically. Do not induce vomiting.

**IDENTIFICATION AND PRESENTATION**

TIGER BALM RED is a reddish-brown, oily ointment. The ointment is supplied in screw top glass jars containing 19 g or 30 g. Not all pack sizes may be marketed.

**STORAGE INSTRUCTIONS**

Store in a cool, dry place at or below 30 °C. Keep the jar tightly closed.

Keep out of reach and sight of children.

**REGISTRATION NUMBER**

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

**MANUFACTURED BY**

Xiamen Tiger Medicals Co. Ltd., for Haw Par Healthcare Ltd., Singapore under licence from Haw Par Corporation Ltd.

Manufacturer's Address: No 289, West Yangguang Road, Haicang District, Xiamen City, Fujian Province, China

**NAME AND ADDRESS OF THE PROPOSED HOLDER OF CERTIFICATE OF REGISTRATION**

Abex Pharmaceutica (Pty) Ltd; Rubenstein Ridge Suite C, 617 Rubenstein Drive; Moreleta Park; 0181

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